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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/612,894

Applicant(s)
Stocco et al.

Examiner
Jezia Riley

Group Art Unit
1656



Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

☒ Claims 1-36 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-13 and 20, drawn to a nucleic acid compositions, classified in Class 536, subclass 23.1.

II. Claims 14-17, drawn to a protein, classified in Class 530, subclass 350.

III. Claims 18 and 19, drawn to method of preparing a protein, classified in Class 435, subclasses 69.1.

IV. Claims 21-26, drawn to an antibody, classified in Class 530, subclass 388.1.

V. Claims 27 and 28, drawn to an immunoassay, classified in Class 435, subclass 7.1.

VI. Claims 29-33, drawn to a hybridization assay, classified in Class 435, subclass 6.

VII. Claims 34-36, drawn to methods for administering a pharmacologically amount of protein, classified in Class 514, subclasses 1 and 2; Class 424, subclass 184.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and IV are independent inventions because they are drawn compositions having different chemical structures, physical properties and utilities, requiring different searches and raising different issues of ennoblement and prior art regarding the critical limitations therein. For Group I the

critical feature is a nucleic acid, for Group II the critical feature is polypeptide whereas for Group III the critical feature is antibody. It is acknowledged that various processing steps may cause a polypeptide of Group II to be directed as to its synthesis by DNA of Group I, however the completely separate classification of the inventions supports the undue search burden if all the inventions were examined together. Also it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if not limited as to additions, subtractions, etc.

Inventions III, V, VI, and VII are disclosed as different combinations which are not connected in design, operation or effect. These combinations are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the combinations of the therapeutic techniques of Group VII have different functions and effects than the detecting method of Group V, the hybridization assay of Group VI, or the method of Group III for example.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibody of IV can be used in affinity purification, for example.

Inventions I, III, and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acid acid of I can be used in a polymerase chain reaction assay, for example.

Inventions II and V and VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein of II can be used as catalyst in a chemical reaction, for example.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can

be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein of Group II can be chemically synthesized.

Inventions I and V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions IV, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions are not disclosed as capable of use together.

Inventions III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III has separate utility such as it can be used in methods of Group VII and invention IV can be used in the method of Group V, for example. See MPEP § 806.05(d).

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

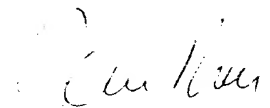
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is (703) 305-6855. The examiner may normally be reached Monday through Friday, 0900 - 1700 EST. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Gary Jones, may be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix Receptionist whose telephone number is (703) 308-0196.

Any necessary fax can be sent to (703) 308-4242.


JEZIA RILEY
PRIMARY EXAMINER